

**REMARKS****I. Status of the Claims**

Claims 1-3, 5, 6 and 9-15 are pending in this application. Claims 1 and 10 have been amended to more clearly define that which Applicants regard as their invention. Support for the amendment to claim 1 can be found in original claim 4. Support for the amendment to claim 10 can be found in the specification at least at page 2, lines 8-9. Claim 4 has been canceled as the limitations thereof have been incorporated into claim 1. Accordingly, no new matter has been introduced by this Amendment.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version With Markings To Show Changes Made."

**II. Rejections Under 35 U.S.C. § 102 (a) and (e)***A. The Rejection over U.S. Patent No. 6,365,623**Keep*

The Examiner has rejected claims 1-5 as allegedly anticipated by U.S. Patent No. 6,365,623 ("Perricone '623"). Applicants respectfully traverse this rejection because Perricone '623 fails to teach or suggest all of the claim limitations of claims 1-5.

Perricone relates to a method for reducing and preventing acneiform scars and reducing pore size. The method comprises topically applying to affected skin areas a composition containing lipoic acid or a lipoic acid derivative in a dermatologically acceptable carrier.

Perricone '623 fails to anticipate Applicants' claimed method for ameliorating redness or inflammation of mammalian skin by topically applying to red or inflamed mammalian skin a composition comprising an effective amount of a redness or inflammation reducing agent selected from an alkanolamine, tyrosine or a mixture thereof and a cosmetically acceptable carrier.

In response to Applicants arguments, the Examiner argues that the "recited method steps in the instant claims are disclosed in the reference." Applicants respectfully disagree. As discussed

above, nowhere does Perricone '623 teach or suggest a method for ameliorating redness or inflammation of mammalian skin. The Examiner also argues that Perricone '623 specifically discloses the inclusion of 0.5-5% by weight of dimethylaminoethanol (col. 8, line 41) and 0.05 to 5.0% tyrosine (col. 9, line 23). However, as discussed above, these ingredients are taught by Perricone '623 to be "adjunct ingredients" and are listed among many other ingredients such as alpha hydroxy acids, tocopherols, fatty acid esters of ascorbic acid, antibiotics and retinoids. Perricone '623 fails to teach or suggest that alkanolamine and/or tyrosine could be used as redness or inflammation reducing agents in a method for ameliorating redness or inflammation of mammalian skin. For all these reasons, Applicants respectfully request withdrawal of this rejection.

B. *The Rejection Over U.S. 6,319,942 ("Perricone '942")*

The Examiner has rejected claims 1-5 as allegedly anticipated by Perricone '942. Perricone '942 relates to methods for the treatment or inhibition of cutaneous scar tissue. There is no teaching or suggestion of a method for ameliorating redness or inflammation of skin. The Examiner argues that Perricone '942 teaches that the formation of scars undergo inflammatory stage and that hypertrophic and keloid scars show inflammatory activity. The fact that some stages or some scars undergo an inflammatory stage is irrelevant to Applicants claimed method for ameliorating redness or inflammation of mammalian skin. Clearly, Perricone '942 specifically relates to the treatment of cutaneous scar tissue. Although Perricone '942 recognizes the different stages in the formation of scars there is no teaching or suggestion of a method for ameliorating redness or inflammation of mammalian skin. Accordingly, Applicants respectfully submit that Perricone '942 cannot anticipate the present claims.

C. *The Rejection Over U.S. 5,972,993 ("Ptchelintsev")*

The Examiner has rejected claims 1, 2 and 10 as allegedly anticipated by Ptchelintsev. Claim 1 now includes the limitations of claim 4 which was not rejected by the Examiner. Accordingly, Applicants respectfully request withdrawal of this rejection.

### III. Rejections Under 35 U.S.C. § 103

#### A. The Rejection Over WO 00/9804280 ("Toth")

The Examiner has rejected claims 1-3 as allegedly unpatentable over Toth. Claim 1 now includes the limitations of claim 4 which was not rejected by the Examiner. Accordingly, Applicants respectfully request withdrawal of this rejection.

#### B. The Rejection Over Perricone '942 In View Of U.S. Patent No. 5,968,532 ("de Lacharriere")

The Examiner has rejected claims 6 and 9-15 as allegedly unpatentable over Perricone '942 as applied to claims 1-5 above and further in view of U.S. Patent No. 5,968,532 ("de Lacharriere"). Applicants respectfully traverse this rejection.

Claim 6 relates to a method according to claim 1, wherein said composition further comprises a skin irritating ingredient selected from a retinoid, benzoyl peroxide, alpha-hydroxyacids and derivatives thereof, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives, urea, preservatives.

Claim 9 relates to a method for ameliorating redness or inflammation of mammalian skin as recited in claim 1, wherein the composition is applied to sun burned skin, wind burned skin or skin that is red or inflamed due to contact with irritating soaps or cleansers. Claim 10 relates to a method according to claim 1, wherein the composition is applied to skin that is red or inflamed due to rosacea, atopic dermatitis or allergic skin reactions.

Claims 11-15 relate to a method for ameliorating the irritating effects of a skin irritating composition comprising adding to said composition an effective amount of a compound selected from the group consisting of an alkanolamine; tyrosine; or a mixture thereof wherein said skin irritating compositions comprises at least one compound selected from retinoid, benzoyl peroxide, alpha-hydroxyacids and derivatives thereof, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives, urea, and preservatives.

Perricone '942 relates to a method for or the treatment or inhibition of cutaneous scar tissue comprising applying to said tissue a composition containing an effective amount of an alkanolamine. The Examiner recognizes that Perricone '942 "fails to teach treating redness or inflammation caused

by the irritants recited in the instant claims." The Examiner then relies upon de Lacharriere to cure these deficiencies of Perricone '942.

It is the Examiner's position that it would have been obvious to one of ordinary skill in the art "to have modified the method of treating scars or inflamed skin condition described in Perricone '942 by applying the composition therein to reddened or inflamed skin caused by the irritants or damaged by the environments as motivated by de Lacharriere." The Examiner further states that "the skilled artisan would have expected that the composition that is effective in treating inflammatory scar wounds would be similarly effective in reducing inflammation or the associated symptoms caused by other factors." Applicants respectfully disagree.

As the Examiner is well aware, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference(or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

Here, neither Perricone '942 nor de Lacharriere provide any suggestion or motivation to modify the methods taught by Perricone '942 as suggested by the Examiner. Perricone '942 relates to a method for or the treatment or inhibition of cutaneous scar tissue. On the other hand, de Lacharriere relates to the use of an ethylenediamine derivative as a substance P antagonist and /or as a local analgesic in, or for the preparation of, a cosmetic or dermatological composition for treating sensitive skin types. There is no teaching or suggestion in de Lacharriere that the compositions taught therein could be used in a method for treating scars such as taught by Perricone '942.

It appears to be the Examiner's position that because de Lacharriere teaches treating dysaesthetic sensations, de Lacharriere somehow provides one of ordinary skill in the art with the expectation that the methods for treating scars taught by Perricone could be used to ameliorate redness or inflammation of mammalian skin. Applicants respectfully disagree. Simply because de Lacharriere teaches a method for treating dysaesthetic sensations does not provide the requisite motivation for expanding the methods taught by Perricone to include methods for ameliorating

redness or inflammation of mammalian skin. Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and the rejection should be withdrawn.

#### IV. Conclusion

Applicants believe that the foregoing presents a full and complete response to the outstanding Office Action. An early and favorable response to this Amendment is earnestly solicited. If the Examiner feels that a discussion with Applicants' representative would be helpful in resolving the outstanding issues, the Examiner is invited to contact Applicants' representative at the number provided below.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP-525/EMH. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,



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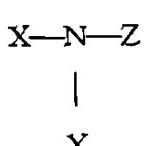
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1 (three times amended) A method for ameliorating redness or inflammation of mammalian skin, comprising the step of topically applying a composition to red or inflamed mammalian skin, said composition comprising:

- (c) [an effective amount] from about 0.1 to about 10% by weight, based on the total composition, of a redness or inflammation reducing agent selected from an alkanolamine, tyrosine or a mixture thereof; and
- (d) a cosmetically acceptable carrier;
- wherein said alkanolamine has the following general formula:



wherein X, Y and Z are selected from the group consisting of hydrogen, C<sub>1</sub>-C<sub>3</sub> alkyl group, C<sub>2</sub>-C<sub>4</sub> alkanol group, wherein at least one of X, Y or Z is a C<sub>2</sub>-C<sub>4</sub> alkanol group bearing at least one hydroxyl group and optionally at least one carboxyl group.

10 (Amended). A method according to claim 1, wherein said composition is applied to skin that is red or inflamed due to acne lesions, rosacea, atopic dermatitis, or allergic skin reactions.

Please cancel claim 4 without prejudice or disclaimer.